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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ALLISON OTTESEN, SEAN ALLEN, and LAUREN ACCARDI, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

HI-TECH PHARMACEUTICALS, INC.,

Defendant.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Allison Ottesen, Sean Allen, and Lauren Accardi ("Plaintiffs") make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION

1. This is a class action lawsuit on behalf of purchasers of Hi-Tech Pharmaceuticals Inc.'s ("Defendant" or "Hi-Tech") Ultimate Orange, HydroxyElite, Lipodrene Elite, Lipodrene, Lipodrene Hardcore, Lipodrene Xtreme, Synadrene, Jack'd Up, Stimerex-ES, Stimerex Hardcore, Fastin, Fastin-XR, and Black Widow supplements containing the stimulant DMHA (collectively, "Supplements").

2. DMHA is illegal and is not generally recognized among experts to be safe under the conditions of its intended use. Defendant is breaking the law by manufacturing and distributing supplements containing the stimulant DMHA and failing to disclose that they contain an ingredient that is illegal and not generally recognized as safe.

3. Defendant has a long history of using illegal and unsafe ingredients in the Supplements. The Supplements were originally manufactured with an ingredient called DMAA, also a powerful and dangerous stimulant ingredient.

4. But in the wake of a rash of high-profile incidents relating to DMAA use, including the death of multiple U.S. Military servicemembers, the use of DMAA in the Supplements was determined by the U.S. Food and Drug Administration and a federal court in Georgia to be illegal and federal authorities seized $19 million worth of DMAA from Defendant in order to protect consumers. The court's decision regarding the illegality of DMAA was subsequently affirmed by the United States Court of Appeals for the Eleventh Circuit. *See United States v. Undetermined Quantities of All Articles of Finished & In-Process Foods*, 936 F.3d 1341, 1351 (11th Cir. 2019).

5. Notwithstanding this, Defendant sought to continue use of DMAA in the Supplements. However, in late 2017, Defendant, along with Jared Wheat (Defendant's owner) and John Brandon Schopp (Defendant's Director of Contract Manufacturing), was indicted in the

Northern District of Georgia for, among other things, wire fraud and money laundering. *See U.S. v. Jared Wheat et al.*, No. 1:17-cr-0229 (N.D. Ga. 2017). As part of the conditions of release, Defendant, along with Wheat and Schopp, were barred from selling products containing DMAA "or its chemical equivalent."

6. Unable to use DMAA, Defendant has replaced it in the Supplements with a compound called "DMHA." But, as it pertains to legality and safety, there is no difference between DMAA and DMHA. In fact, Defendant itself has explained that while "DMAA is not the chemical equivalent of DMHA, it does have a very similar structure and thus, the two ingredients could be expected to produce similar effects in humans."

7. Unsurprisingly, the FDA was displeased that Defendant simply substituted one illegal drug for another in its switch from DMAA and DMHA. On April 10, 2019, the FDA sent a warning letter to Hi-Tech regarding the use of the DMHA ingredient in its products. The warning letter states that DMHA "is not generally recognized as safe under its conditions for use in Hi-Tech's dietary supplement products."[1] The FDA explained that there is no evidence that "DMHA was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has been chemically altered."[2] Moreover, the FDA concluded that "dietary supplements containing DMHA as a new dietary ingredient are adulterated … because there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."[3]

8. Published academic literature has confirmed that the "uncontrolled use of [DMHA], its physiological and psychoactive effects raise serious health implications with possible impact on athletes and doping practices."[4]

[1] The FDA's April 10, 2019 warning letter is attached hereto as **Exhibit A**.
[2] *See* Ex. A, at 2.
[3] *Id.* at 2-3.
[4] Catalani, Valeria et al. "Octodrine: New Questions and Challenges in Sport Supplements." *Brain sciences* vol. 8,2 34. 20 Feb. 2018, doi:10.3390/brainsci8020034.

9. Plaintiffs and class members were never informed of any of this. They are unsuspecting purchasers of the Supplements who were never informed that the Supplements are illegal and not generally recognized as safe. They therefore assert claims for fraud, breach of warranty, and violations of the consumer protection laws of California and New York on behalf of themselves and all other similarly situated purchasers of the Supplements.

PARTIES

10. Plaintiff Allison Ottesen is a citizen of California who resides in Oakland, California. Ms. Ottesen purchased HydroxyElite supplements for personal use from retailer Same Day Supplements in or around late 2018. Ms. Ottesen paid approximately $34.95 for the HydroxyElite supplements. Ms. Ottesen purchased and used Defendant's HydroxyElite supplements based on the understanding that the supplements were lawfully sold and did not contain illegal and unsafe stimulants. Had Defendant disclosed that the Supplements are unsafe and illegal, Ms. Ottesen would have been aware of that and would not have purchased the Supplements

11. Plaintiff Sean Allen is a citizen of New York who resides in Watertown, New York. Mr. Allen purchased the HydroxyElite and Lipodrene supplements for personal use from retailer Impact Nutrition 315 in Watertown, New York in or around April 2017. Mr. Allen paid approximately $29.99 for HydroxyElite and approximately $32.99 for Lipodrene. Mr. Allen purchased and used Defendant's HydroxyElite and Lipodrene supplements based on the understanding that the supplements were lawfully sold and did not contain illegal and unsafe stimulants. Had Defendant disclosed that the Supplements are unsafe and illegal, Mr. Allen would have been aware of that and would not have purchased the Supplements.

12. Plaintiff Lauren Accardi is a citizen of New York who resides in East Islip, New York. Ms. Accardi purchased HydroxyElite supplements for personal use from retailer Same Day Supplements. Ms. Accardi paid approximately $39.95 for the HydroxyElite supplements on numerous occasions between 2015 and July 2019. Ms. Accardi purchased and used Defendant's HydroxyElite supplements based on the understanding that the supplements were lawfully sold and

did not contain illegal and unsafe stimulants. Had Defendant disclosed that the Supplements are unsafe and illegal, Ms. Accardi would have been aware of that and would not have purchased the Supplements.

13. Defendant Hi-Tech Pharmaceuticals, Inc. is a Georgia limited liability company with its principal place of business at 6015 B Unity Drive, Norcross, GA 30071. Defendant manufactured, distributed, and sold the Supplements throughout the United States. Defendant affirmatively participated in the false and misleading advertising and marketing claims about the Supplements.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A) because this case is a class action where the aggregate claims of all members of the proposed Class are in excess of $5,000,000.00, exclusive of interest and costs, and Plaintiffs and most members of the proposed Class are citizens of states different than Defendant.

15. This Court has personal jurisdiction over Defendant because Plaintiff Ottesen purchased Defendant's HydroxyElite product in this District, Defendant does substantial business in California, intentionally availed itself of the markets in California through the promotion, marketing, and sale of the Supplements, and conducts substantial business within California such that it has significant continuous and pervasive contacts with the State of California sufficient to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

16. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to these claims occurred in this District.

FACTS COMMON TO ALL CAUSES OF ACTION

A. Overview of the Supplements

17. Hi-Tech manufactures, distributes and sells the Supplements, which contain the illegal ingredient and powerful stimulant DMHA.

18. On the packaging of each of the Supplements, Defendant represents that each of the Supplements are a "Dietary Supplement."[5]

19. Each of the Supplements were originally manufactured with DMAA. However, after the FDA's ban on DMAA, Hi-Tech simply reformulated the Supplements with DMHA in an attempt to stay one step ahead of the proverbial sheriff.

20. By Hi-Tech's own admission, DMAA and DMHA are so similar that they are "expected to produce similar effects in humans."

21. Nowhere in Defendant's labeling or marketing of the Supplements does Defendant disclose that the Supplements contain illegal ingredients that are not generally recognized as safe for use as described on the label. Defendant does not disclose the true nature of the Supplements to consumers.

B. History Of The Supplements And DMHA

22. As a result of the very competitive landscape for manufacturers of fat burning and pre-workout supplements, an increasingly widespread issue in recent years has been that certain dietary supplement manufacturers have illegally used pharmaceutical and often dangerous drugs in over-the-counter supplement products without informing consumers of the true nature of the products or the dangers associated therewith. This is especially prevalent in the realm of stimulants, as discussed below.

23. For years, Hi-Tech has been at the center of the controversy as it relates to illegal stimulant ingredients.

24. As described above, Hi-Tech originally manufactured the Supplements using the illegal stimulant ingredient DMAA.

25. DMAA was patented and submitted to the FDA for approval as a decongestant in the 1940s.[6] The compound had an approved new drug application and was sold as an over-the counter drug until 1983. DMAA is a vasoconstrictor and a central nervous system stimulant which

[5] https://hitechpharma.com/collections/all-products (last visited 10/28/19).
[6] DMAA was patented by Eli Lilly and Company in 1944 (U.S. Patent # 2,350,318) and marketed for sale as a drug under the brand name Forthane for the use in the relief of nasal congestion.

is on the World Anti-Doping Agency ("WADA") and Major League Baseball ("MLB") lists of banned substances. DMAA is related to amphetamine and can cause high blood pressure, nausea, cerebral hemorrhage, stroke, and, in serious cases, can be fatal. DMAA is banned in Canada, New Zealand, Finland, and Ireland. Moreover, the United States military has removed DMAA-containing supplements from all military exchanges worldwide following the sudden deaths of two soldiers who were users of DMAA pre-workout supplements.[7]

26. DMAA drew the attention of the FDA, which quickly took action to eliminate the DMAA ingredient from dietary supplement products. Indeed, in 2013, the FDA stated that it was "using all available tools at its disposal to ensure that dietary supplements containing a stimulant called dimethylamylamine (DMAA) are no longer distributed and available for sale to consumers in the marketplace."[8]

27. Despite the FDA's efforts, Hi-Tech persisted in using DMAA in the Supplements. In 2013, "the FDA seized DMAA-containing products from Hi-Tech Pharmaceuticals; a federal district court ruled in April 2017 that the products were adulterated and ordered them condemned and forfeited to the United States for destruction."[9] The judge held that "products for human consumption containing DMAA are adulterated foods under the FDCA and subject to seizure pursuant to 21 U.S.C. § 334." *United States v. Quantities of Finished & In-Process Foods*, No. 1:13-CV-3675-WBH, 2017 WL 4456903, at *4 (N.D. Ga. Apr. 3, 2017), *aff'd sub nom. United States v. Undetermined Quantities of All Articles of Finished & In-Process Foods*, 936 F.3d 1341 (11th Cir. 2019).

28. On August 30, 2019, in a published decision, the United States Court of Appeals for the Eleventh Circuit affirmed the district court's decision, and concluded that DMAA was not a "dietary supplement," and was not generally recognized as safe under the conditions of its intended

[7] https://www.nytimes.com/2012/02/03/business/army-studies-workout-supplements-after-2-deaths.html (last visited 10/28/19).
[8] https://www.fda.gov/consumers/consumer-updates/stimulant-potentially-dangerous-health-fda-warns (last visited 10/28/19).
[9] https://www.fda.gov/food/dietary-supplement-products-ingredients/dmaa-products-marketed-dietary-supplements (last visited 10/28/19).

use. *United States v. Undetermined Quantities of All Articles of Finished & In-Process Foods*, 936 F.3d 1341, 1351 (11th Cir. 2019).

29. Not only was Hi-Tech in the midst of a battle with the FDA, but Hi-Tech and its owner Jared Wheat, as well as John Brandon Schopp were indicted in the Northern District of Georgia for, among other things, wire fraud and money laundering. *See U.S. v. Jared Wheat et al.*, No. 1:17-cr-0229 (N.D. Ga. 2017).

30. Hi-Tech was arraigned on October 4, 2017, and on that date the court issued an Order stating that "Hi-Tech is prohibited from, directly or indirectly through third parties, manufacturing, distributing or selling adulterated foods or misbranded drugs, including but not limited to products containing DMAA or its chemical equivalent. This includes but is not limited to: purchasing or receiving DMAA ingredients; and manufacturing, processing, packaging, marketing, or distributing food or dietary supplement products containing DMAA or its chemical equivalent." *See U.S. v. Hi-Tech Pharmaceuticals, Inc., et al.*, No. 1:17-cr-00229 (N.D. Ga. 2017) (Dkt. No. 19).

31. Mr. Wheat posted an appearance bond in the criminal action. One of the bond conditions is that "Defendants are prohibited from, directly or indirectly through third parties, manufacturing, distributing or selling adulterated foods or misbranded drugs." *Id.* (Dkt. No. 22-1).

32. Adding a third layer, Hi-Tech's use of DMAA in its products was also the subject of a prior consumer class action complaint. *Morgan Kaczor v. Hi-Tech Pharmaceuticals, Inc.*, Case No. 12-cv-04089 (C.D. Cal.).

33. In the midst of Hi-Tech's legal battles with the FDA over the DMAA ingredient, as well as the ongoing criminal charges, Hi-Tech reformulated the Supplements with an equally dangerous and related compound, DMHA.

34. Just like their predecessors manufactured with DMAA, Defendant labels the Supplements for sale as "dietary supplement[s]." The Supplement Facts panel on the Supplements' labels declares 2-Aminoisehptane HCI as an ingredient. This ingredient is also called, among other names, 1,5-DMHA, 2-amino-6-methylheptane, 2-amino-5methylheptane, 1,5-

Dimethylhexylamine, 2-Isooctyl amine, and Octodrine. These ingredients are collectively referred to under the name DMHA.[10]

35. DMHA has a similar history to that of DMAA. The FDA approved DMHA as a new drug in 1946 for use by nasal administration. The drug company Smith, Kline, and French introduced DMHA as the active ingredient in the Eskay® Oralator inhaler.

36. Like DMAA, DMHA is banned by the United States Anti-Doping Agency,[11] the World Anti-Doping Agency,[12] the Department of Defense,[13] and the NCAA.[14]

37. DMHA has also been banned in other countries. In 2017, the Australian Therapeutic Goods Association banned DMHA "due to risks to human health."[15]

38. DMHA, like DMAA, is a dangerous amphetamine-like stimulant that poses serious health risks and has potentially life-threatening side effects.

39. Both DMHA and DMAA can cause high blood pressure, nausea, cerebral hemorrhage, and stroke.

40. Hi-Tech has recently admitted that DMHA is similar to DMAA, stating: "According to [Hi-Tech's] expert, while DMAA is not the chemical equivalent of DMHA, it does have a very similar structure and thus, the two ingredients could be expected to produce similar effects in humans."[16]

41. As such, DMHA carries with it the same dangers and concerns as products containing DMAA.

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[10] https://www.fda.gov/food/dietary-supplement-products-ingredients/dmha-dietary-supplements (last visited 10/12/19).
[11] https://www.usada.org/spirit-of-sport/education/octodrine/ (last visited 10/13/19).
[12] https://www.wada-ama.org/sites/default/files/wada_2020_english_prohibited_list_0.pdf (last visited 10/13/19).
[13] https://www.opss.org/dietary-supplement-ingredients-prohibited-department-defense (last visited 10/13/19).
[14] http://www.ncaa.org/sport-science-institute/topics/2019-20-ncaa-banned-substances (last visited 10/13/19).
[15] https://www.asada.gov.au/news/supplement-ingredients-banned (last visited 10/13/19).
[16] *Hi-Tech Pharmaceuticals, Inc., and Jared Wheat v. Norman E. Sharpless, M.D., as Commissioner of the United States Food and Drug Administration, et al.*, Case No. 1:19-cv-1268 (D.D.C.) (Dkt. No. 7, at 3-4).

42. DMHA carries additional side effects "such as mood swings, tremor, concentration deficiency, over-stimulation, energy crashes, anxiety, high blood pressure, dyspnea, rapid heartbeat and heartburn."[17]

43. Like DMAA, DMHA is not "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures ... to be safe under the conditions of its intended use." 21 U.S.C. § 321(s). *United States v. Undetermined Quantities of All Articles of Finished & In-Process Foods*, 936 F.3d 1341, 1348-1350 (11th Cir. 2019) (concluding that DMAA is not generally recognized as safe).

44. Scholarly literature supports this conclusion as to DMHA, finding that "uncontrolled use of [DMHA], its physiological and psychoactive effects raise serious health implications with possible impact on athletes and doping practices."[18] The study states: "[T]he lack of experimental randomized controlled trials (RCTs) and other interventional studies on humans has led to a complete absence of systematic reviews and meta-analytic studies related to use of Octodrine as a medicinal agent or food supplement."[19] As such, it cannot be said that DMHA is generally recognized as safe for use as directed by Defendant. Defendant knew as much, and intentionally failed to meet statutory requirements relevant to use of DMHA.

45. The FDA stepped in and issued the April 10, 2019 warning letter to Defendant stating that the Supplements are adulterated, as discussed below.

C. Defendant Broke the Law By Putting DMHA In The Supplements

46. As manufacturer and distributor of the Supplements, Defendant had an affirmative duty to comply with the FDCA, as well as any parallel state statutes, including the California Sherman Law.

47. As explained below, the inclusion of DMHA in the Supplements is illegal for two reasons. First, because it is not properly categorized as a "dietary supplement," it is an illegal

[17] Catalani, Valeria et al. "Octodrine: New Questions and Challenges in Sport Supplements." *Brain sciences* vol. 8,2 34. 20 Feb. 2018, doi:10.3390/brainsci8020034

[18] Catalani, Valeria et al. "Octodrine: New Questions and Challenges in Sport Supplements." *Brain sciences* vol. 8,2 34. 20 Feb. 2018, doi:10.3390/brainsci8020034.

[19] *Id.*

"unsafe food additive." Second, even if it were a dietary supplement, Defendant still failed to comply with procedures required under the FDCA.

DMHA Is An Unsafe Food Additive

48. In 1994, the Dietary Supplement Health and Education Act ("DSHEA") was passed into law as an amendment to the FDCA, establishing a new framework governing the composition, safety, labeling, manufacturing, and marketing of dietary supplements.

49. Dietary supplements are defined by the FDCA as a "product (other than tobacco) intended to supplement the diet" that contains one or more of the following: (1) vitamins; (2) minerals; (3) and herb or other botanical; (4) an amino acid; (5) a supplement meant to increase total dietary intake; (6) a concentrate, metabolite, constituent, extract, or combination of any of the listed ingredient. 21 U.S.C. § 321(ff)(1).

50. The Supplements do not meet the definition of a "Dietary Supplement" because DMHA is, in fact, a synthetically-produced "unsafe food additive." As such, DMHA cannot be legally included in any over-the-counter supplement product, and the Supplements are adulterated. The FDA concurred with this analysis in its April 2019 warning letter, stating: "DMHA it is not generally recognized as safe under its conditions of use in your dietary supplement products. If DMHA is not a dietary ingredient under section 201(ff)(1) of the Act, dietary supplements containing DMHA would be adulterated under section 402(a)(2)(C)(i) of the Act because they would contain an unsafe food additive."

51. Indeed, the Eleventh Circuit, in analyzing the closely-related DMAA against the definition of "Dietary Supplement" in the FDCA, affirmed the FDA's decision to classify DMAA as an "unsafe food additive."

52. Like DMAA, Defendant synthetically produces DMHA for use in the Supplements. DMHA does not meet any of the criteria to be considered a "Dietary Supplement." Defendant misrepresents the Supplements as "Dietary Supplement[s]," when in fact they are not. The Supplements are therefore adulterated.

Defendant Failed To Comply With Requirements For New Dietary Ingredients

53. Even if the Supplements could somehow be considered "Dietary Supplements," which they cannot, they are still unlawfully sold because they are otherwise adulterated and misbranded because Defendant failed to comply with requirements for new dietary ingredients.

54. Under the FDCA, a "New Dietary Ingredient" ("NDI") is defined as a "dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994." 21 U.S.C. § 350b(d).

55. DMHA was not marketed in the United States before 1994 (*i.e.* before the passage of the DSHEA). The FDA's April 2019 warning letter reached an identical conclusion. The FDA explained that there is no evidence that "DMHA was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has been chemically altered."[20]

56. Therefore, even assuming DMHA could be considered a dietary supplement, DMHA would still be legally considered a NDI.

57. Under the FDCA, a dietary supplement containing a NDI may only be only be marketed and sold if it meets one of two requirements:

> (1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered [or]
>
> (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement

[20] *See* Ex. A, at 2.

> containing such dietary ingredient will reasonably be expected to be safe.

21 U.S.C. § 350b(a).

58. However, Defendant has never complied with these requirements.

59. Defendant failed to comply with the FDA's NDI notification requirement that is mandated for all dietary supplements that contain NDIs which, like DMHA, have not been "present in the food supply as articles used for food without being chemically altered." 21 U.S.C. § 350b(a)(1).

60. Defendant also failed to provide the FDA with the required 75-day premarket notification showing a history of DMHA's harmless use in food products/supplements or any other evidence of safety.

61. What is more, Defendant could not have met the requirements of 21 U.S.C. § 350b(a) regardless, as there is no "history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling." Indeed, the FDA explained:

> Even if a new dietary ingredient notification had been submitted under section 413(a)(2) and 21 CFR 190.6, we know of no evidence that would establish that DMHA could be lawfully marketed as a new dietary ingredient in your Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene products. In the absence of a history of use or other evidence of safety establishing that DMHA, when used under the conditions recommended or suggested in the labeling as a dietary ingredient, will reasonably be expected to be safe, dietary supplements containing DMHA as a new dietary ingredient are adulterated under sections 402(f) and 413(a) of the Act because there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under sections 301(a) and (v) of the Act [21 U.S.C. § 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that DMHA will reasonably be expected to be safe when used as a dietary ingredient.[21]

[21] *See* Ex. A.

62. As such, the Supplements are separately adulterated because Defendant did not follow the statutory procedure for introducing a NDI into commerce. Defendant failed to do this because it knows that DMHA is in fact an unsafe food additive, and also knows that there is no evidence establishing the safety of DMHA when used as recommended by Defendant.

63. In light of the foregoing, the Supplements are::

- misbranded under 21 U.S.C. § 343(a);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is "adulterated" and "misbranded");
- unsafe and adulterated under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331(v); and
- not legal for sale because it includes an article approved as a drug for which clinical trials have been made public under 21 U.S.C. § 331(11).

The Supplements Violate California, New York And Federal Law

64. California's Sherman Food, Drug, and Cosmetic Law expressly incorporates all food labeling requirements set forth in the FDCA (*see* Cal. H&S Code § 110100(a)), and further provides that any food is misbranded if its nutrition labeling does not conform to FDCA requirements (*see* Cal. H&S Code §§ 110665, 110670, 110673).

65. New York has also expressly adopted the federal food labeling requirements of §343(1) and (a)(1) into state law pursuant to New York's Agriculture and Marketing law. N.Y. Agric. & Mkts. Law § 201.

66. New York's Agriculture and Marketing law incorporates the FDCA's labeling provisions and, likewise, provides that food shall be deemed misbranded "[i]f its labeling is false or misleading in any particular." Accordingly, a violation of federal food labeling laws is also an independent violation of New York law and actionable as such.

67. New York law also provides remedies, including private rights of action, for misbranding food under consumer protection laws, including GBL § 349, which broadly prohibits use of "deceptive acts or practices" in business dealings in New York.

68. Pursuant to the FDCA, and accordingly California and New York law, food products that are misbranded cannot legally be manufactured, advertised, distributed, held or sold. Because misbranded products cannot be legally sold or possessed, they have no economic or legal value. Plaintiffs and Members of the Classes who purchased the Products paid an unwarranted amount for these Products.

69. Defendant's misleading and deceptive practices proximately caused harm to Plaintiffs and Class members. Defendants have sold Products that are worthless because they could not be lawfully sold to consumers.

CLASS ACTION ALLEGATIONS

70. Plaintiffs seek to represent a class defined as all persons in the United States who purchased the Supplements (the "Class"). Excluded from the Class are governmental entities, Defendant, Defendant's affiliates, parents, subsidiaries, employees, officers, and directors. Also excluded is any judicial officer presiding over this matter and the members of their immediate families and judicial staff.

71. Plaintiff Ottesen also seeks to represent a subclass defined as all persons who purchased the Supplements in California (the "California Subclass").

72. Plaintiffs Allen and Accardi also seek to represent a subclass defined as all persons who purchased the Supplements in New York (the "New York Subclass").

73. Members of the Class and the California and New York Subclasses are so numerous that their individual joinder herein is impracticable. On information and belief, members of the Class and the New York and California Subclasses number in excess of tens of thousands. The precise number of Class members and their identities are unknown to Plaintiffs at this time but will be determined through discovery. Class members and members of the California and New York Subclasses may be discerned through Defendant's records and through third-party subpoenas of

retailers of Defendant's products. Class members and members of the California and New York Subclasses may be notified of the pendency of this action by mail, email, and/or publication.

74. Common questions of law and fact exist as to all Class, California Subclass and New York Subclass members and predominate over questions affecting only individual Class and New York and California Subclass members. These common legal and factual questions include, but are not limited to: (a) whether Defendant's conduct violates UCC § 2-607(3)(a) concerning the breach of implied warranties; (b) whether the Supplements contain the ingredient DMHA; (c) whether the DMHA ingredient is an illegal ingredient; (d) whether Defendant was unjustly enriched by selling the Supplements to Plaintiffs and Class members; (e) whether Defendant's conduct should be enjoined; (f) whether the Supplements are adulterated due to the presence of DMHA; and (g) whether the Supplements are misbranded due to the presence of DMHA.

75. Plaintiffs' claims are typical of the claims of the proposed Class, California Subclass, and New York Subclass in that Plaintiffs were exposed to Defendant's false and misleading marketing and promotional materials, purchased the adulterated and mislabeled Supplements, and suffered losses as a result of their purchases. Each Class, California Subclass, and New York Subclass member was subjected to the same conduct, was harmed in the same way, and has claims for relief under the same legal theories.

76. Plaintiffs are adequate representatives of the Class, California Subclass, and New York Subclass because their interests do not conflict with the interests of the Class, California Subclass and New York Subclass members they seek to represent, they have retained counsel competent and experienced in prosecuting class actions, and they intend to prosecute this action vigorously. The interests of Class, California Subclass, and New York Subclass members will be fairly and adequately protected by Plaintiffs and their counsel.

77. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of the Class, California Subclass, and New York Subclass members. Each individual Class member, New York Subclass member, and California Subclass member may lack the resources to undergo the burden and expense of individual prosecution of the complex and

extensive litigation necessary to establish Defendant's liability. Individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of Defendant's liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of the liability issues.

78. Unless a class is certified, Defendant will retain monies received as a result of its conduct that were taken from Plaintiffs and the proposed Class, California Subclass, and New York Subclass members. Unless a class-wide injunction is issued, Defendant will continue to commit the violations of law alleged, and the members of the Class, California Subclass, New York Subclass and the general public will continue to be misled.

COUNT I
Breach of Implied Warranty of Merchantability
(On Behalf of the Nationwide Class)

79. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth here.

80. Plaintiffs bring this claim individually and on behalf of the proposed Class and California and New York Subclasses.

81. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller of the Supplements, impliedly warranted that the Supplements are merchantable as dietary supplements.

82. Defendant breached the warranty implied in the contract for the sale of the Supplements because the Supplements could not pass without objection in the trade under the contract description, the goods were not of fair average quality within the description, and the goods were unfit for their intended and ordinary purpose because the Supplements manufactured,

distributed, and sold by Defendant contained the dangerous stimulant DMHA, which is an unsafe food additive and is otherwise illegal for sale as a dietary supplement in the United States. As a result, Plaintiffs and Class members did not receive the goods as impliedly warranted by Defendant to be merchantable.

83. Plaintiffs and Class members purchased the Supplements in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

84. The Supplements were not altered by Plaintiffs or Class members.

85. The Supplements were defective when they left the exclusive control of Defendant.

86. Defendant knew that the Supplements would be purchased and used without additional testing by Plaintiffs and Class members.

87. Defendant is a merchant with respect to the goods of this kind that were sold to Plaintiffs and the Class. The sale of the Supplements to Plaintiffs and Class Members contained an implied warranty that the Supplements were merchantable.

88. However, Defendant breached that warranty implied in the contract for the sale of goods in that the Supplements are not "dietary supplements" or generally recognized as safe for use as directed by Defendant, as set forth in detail herein.

89. As a result of Defendant's conduct, Plaintiffs and the Class did not receive goods as impliedly warranted by Defendant to be merchantable.

90. As a direct and proximate cause of Defendant's breach of the implied warranty, Plaintiffs and Class members have been injured and harmed because they would not have purchased the Supplements on the same terms if they knew that they are not generally recognized as safe and illegal.

91. Plaintiffs and the Class have sustained damages as a proximate result of the foregoing breach of implied warranty in an amount to be determined at trial.

COUNT II
Violation of California's Consumers Legal Remedies Act ("CLRA"), California Civil Code §§ 1750, *et seq.*
(On Behalf of the California Subclass)

92. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

93. Plaintiff Allison Ottesen brings this claim individually and on behalf of the California Subclass.

94. Plaintiff Ottesen and the other members of the California Subclass are "consumers," as the term is defined by California Civil Code § 1761(d), because they bought the Supplements for personal, family, or household purposes.

95. Plaintiff Ottesen and the other members of the California Subclass have engaged in "transactions," as that term is defined by California Civil Code § 1761(e).

96. The conduct alleged in this Complaint constitutes unfair methods of competition and unfair and deceptive acts and practices for the purpose of the CLRA, and the conduct was undertaken by Defendant in transactions intended to result in, and which did result in, the sale of goods to consumers.

97. As alleged more fully above, Defendant has violated the CLRA by marketing the Supplements as dietary supplements but failing to inform consumers that the Supplements are not, in fact, "dietary supplements" because they contain an unsafe food additive and a non-dietary ingredient, DMHA. Defendant also failed to inform consumers that DMHA is not generally recognized as safe and is illegal.

98. As a result of engaging in such conduct, Defendant has violated California Civil Code § 1770(a)(5) and (a)(7).

99. On August 12, 2019, a CLRA demand letter was sent to Defendant via certified mail that provided notice of Defendant's violation of the CLRA and demanded that Defendant correct, repair, replace or otherwise rectify the unlawful, unfair, false and/or deceptive practices complained of herein. The letter also indicated that if Defendant refused to do so, a complaint seeking damages in accordance with the CLRA would be filed. Defendant has failed to comply

with the letter. Accordingly, pursuant to California Civil Code § 1780(a)(3), Plaintiff Ottesen, on behalf of herself and all other members of the California Subclass, seeks injunctive relief, compensatory damages, punitive damages, and restitution of any ill-gotten gains due to Defendant's acts and practices. A true and correct copy of the August 12, 2019 letter is attached hereto as **Exhibit B**.

COUNT III
Violation of California's Unfair Competition Law ("UCL"),
California Business & Professions Code §§ 17200, *et seq.*
(On Behalf of the California Subclass)

100. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

101. Plaintiff Ottesen brings this claim individually and on behalf of the California Subclass.

102. Defendant is subject to the Unfair Competition Law ("UCL"), Bus. & Prof. Code §§ 17200 *et seq.* The UCL provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising …."

103. Defendant's sale of the Supplements, described herein, violated the "unlawful" prong of the UCL as a result of its violations of the CLRA, Cal. Civ. Code § 1770(a)(5) and (a)(7) as alleged above. A business act or practice is "unlawful" if it violates any established state or federal law.

104. Defendant's acts, omissions, misrepresentations, practices, and non-disclosures concerning the Supplements, as alleged herein, constitute "unlawful" business acts and practices in that they violate the FDCA, as amended by DSHEA, and implementing regulations, including, at least, the following sections:

a. The prohibition on introduction of adulterated dietary supplements into interstate commerce. 21 U.S.C. § 342(f)(1)(b)

b. The prohibition on introduction of misbranded dietary supplements into interstate commerce. 21 U.S.C. §§ 331, 333; and

c. The requirement prohibiting marketing claims that are "false or misleading in any particular." 21 U.S.C. § 343(a)(1); 21 C.F.R. § 101.93(a)(3).

105. Each of Hi-Tech's violations of federal law and regulations violates California's Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code § 109875 et seq. (the "Sherman Law"), including, but not limited to, the following sections:

a. Section 110100 (adopting all FDA regulations as state regulations);

b. Section 110290 ("In determining whether the labeling or advertisement of a food . . . is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account.");

c. Section 110390 ("It is unlawful for any person to disseminate any false advertisement of any food. . . . An advertisement is false if it is false or misleading in any particular.");

d. Section 110395 ("It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food . . . that is falsely advertised.");

e. Section 110398 ("It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.");

f. Section 110400 ("It is unlawful for any person to receive in commerce any food . . . that is falsely advertised or to deliver or proffer for delivery any such food . . . ."); and

g. Section 110660 ("Any food is misbranded if its labeling is false or misleading in any particular.").

106. Each of the challenged omissions, statements, and actions by Hi-Tech violates the FDCA, as amended by DSHEA, and the Sherman Law, and, consequently, violates the "unlawful" prong of the UCL.

107. Defendant's misrepresentations and other conduct, described herein, violated the "unfair" prong of the UCL in that Defendant's conduct is substantially injurious to consumers,

offends public policy, and is immoral, unethical, oppressive and unscrupulous as the gravity of the conduct outweighs any alleged benefits.

108. Defendant's conduct, described herein, violated the "fraudulent" prong of the UCL by making the omissions concerning the legality of the Supplements.

109. Hi-Tech leveraged its omissions and deception to induce Plaintiff Ottesen and the members of the California Subclass to purchase the Supplements, which were of different characteristics, value, and/or quality than advertised.

110. Hi-Tech's unlawful sales and deceptive marketing and labeling caused Plaintiff Ottesen and the members of the California Subclass to suffer injury in fact and to lose money or property, as it denied them the benefit of the bargain. Had Plaintiff Ottesen and the members of the California Subclass been aware of Hi-Tech's unlawful marketing, labeling, and/or sales tactics, they would not have purchased Hi-Tech's Supplements.

111. Plaintiff Ottesen also seeks an order enjoining Hi-Tech from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and to immediately cease distribution and sale of the Supplements.

112. Plaintiff Ottesen also seeks an order for the disgorgement and restitution of all monies from the sale of the Supplements unjustly acquired through acts of unlawful, unfair, and/or fraudulent competition.

COUNT IV
Violation of New York General Business Law § 349
(On Behalf of the New York Subclass)

113. Plaintiffs incorporate by reference the allegations in the above paragraphs as if fully set forth herein.

114. Plaintiffs Sean Allen and Lauren Accardi bring this claim individually and on behalf of the New York Subclass.

115. By the acts and conduct alleged herein, Defendant engaged in deceptive acts and practices by falsely and misleadingly marketing its Supplements to consumers.

116. The foregoing deceptive acts and practices were directed at consumers.

117. The foregoing deceptive acts and practices are misleading in a material way because had the omitted information been disclosed, Plaintiffs and New York Subclass Members would have been aware of it and not purchased the Supplements.

118. Plaintiffs and members of the New York Subclass were injured because (a) they would not have purchased the Supplements had they known that they contained an illegal and unsafe ingredient. As a result, Plaintiffs and members of the New York Subclass have been damaged in the full amount of the purchase price of the Supplements.

119. As fully alleged above, by advertising, marketing, distribution, and/or selling the Supplements to Plaintiffs and the other members of the New York Subclass, Defendant engaged in and continues to engage in deceptive acts, practices, and omissions.

120. Plaintiffs and the other members of the New York Subclass further seek to enjoin such unlawful deceptive acts and practices as described above. Each of the New York Subclass members will be irreparably harmed unless the unlawful actions of the Defendant are enjoined in that Defendant will continue to falsely and misleadingly sell the Supplements without disclosing their true nature, as set forth at length above. Absent injunctive relief, Defendant will continue to manufacture and sell its Supplements without disclosing that they are illegal and not generally recognized as safe.

121. On behalf of themselves and other members of the New York Subclass, Plaintiffs seek to enjoin the unlawful acts and practices described herein, to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
Fraud
(On Behalf of the Nationwide Class)

122. Plaintiffs incorporate by reference the allegations in the above paragraphs as if fully set forth herein.

123. Plaintiffs bring this claim individually and on behalf of the members of the Class and California and New York Subclasses against Defendant.

124. As discussed above, Defendant failed to disclose to Class members the true nature of, illegality of, and danger associated with, DMHA. Indeed, Defendant markets the Supplements as "Dietary Supplement[s]," which is a uniform representation on the label of each one of the Supplements. However, in truth, Defendant knows that DMHA is not a dietary ingredient, but is in fact a synthetically-produced "unsafe food additive." Defendant further knows that even if DMHA could be considered a dietary ingredient, which it cannot, the Supplements are still adulterated because there is no evidence suggesting that DMHA is safe for use as directed by Defendant.

125. Defendant knew about the dangers associated with DMHA, and intentionally failed to comply with the FDCA and supporting regulations in establishing the safety and efficacy of DMHA as directed on the label. Defendant intentionally failed to meet these obligations because it knows no such evidence exists, and it knows that DMHA is in fact an illegal stimulant and an unsafe food additive.

126. As discussed above, Defendant knew that DMHA carries the same risks and dangers of the previously banned ingredient DMAA, but included DMHA in its products nonetheless.

127. Plaintiffs each purchased Hi-Tech supplements containing the unlawful ingredient DMHA. In purchasing the Supplements, Plaintiffs each reviewed the labels and disclosures, including Defendant's claim that the Supplements were "Dietary Supplement[s]." Plaintiffs relied on Defendant's representations, including that the Supplements were "Dietary Supplement[s]," to their detriment. Had they known the truth about the Supplements, they would not have purchased or used the products.

128. The false and misleading omissions were made with knowledge of their falsehood.

129. The false and misleading representations and omissions were made by Defendant, upon which Plaintiffs and members of the Class and California and New York Subclasses reasonably and justifiably relied, and were intended to induce and actually induced Plaintiffs and Class members to purchase the Supplements.

130. The fraudulent actions of Defendant caused damage to Plaintiffs and members of the Class, who are entitled to damages and other legal and equitable relief as a result.

COUNT VI
Unjust Enrichment
(On Behalf of the Nationwide Class)

131. Plaintiffs incorporate by reference the allegations in the above paragraphs as if fully set forth herein.

132. Plaintiffs bring this claim individually and on behalf of the members of the Class and California and New York Subclasses against Defendant.

133. As a result of Hi-Tech's unlawful and misleading labeling, marketing, and sale of the Supplements, Hi-Tech was enriched at the expense of Plaintiffs.

134. Hi-Tech sold the Supplements to Plaintiffs despite the fact that they were not capable of being sold legally and were worthless.

135. It is against equity and good conscience to permit Hi-Tech to retain the ill-gotten benefits received from Plaintiffs and Class members given that the Supplements were not what Hi-Tech purported them to be.

136. It would be unjust and inequitable for Hi-Tech to retain the benefit, warranting restitutionary disgorgement to Plaintiffs and Class members of all monies paid for the Supplements, and/or all monies paid for which Plaintiffs and Class members did not receive benefit.

137. As a direct and proximate result of Hi-Tech's actions, Plaintiffs and Class members have suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request, individually and on behalf of the alleged Class and California and New York Subclasses, that the Court enter judgment in their favor and against Defendant as follows:

A. An Order certifying the proposed Class and California and New York Subclasses and appointing Plaintiffs and their Counsel to represent the Class and California and New York Subclasses;

B. An Order enjoining Defendant from engaging in the wrongful conduct alleged herein concerning the unlawful, deceptive, fraudulent, harmful, and unfair business conduct and practices;

C. An Order of disgorgement of wrongfully obtained profits;

D. An award of compensatory, statutory, and punitive damages, in an amount to be determined;

E. An award of reasonable attorneys' fees costs and litigation expenses, as allowable by law;

F. Interest on all amounts awarded, as allowed by law; and

G. Such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated: November 4, 2019

Respectfully Submitted,

BURSOR & FISHER, P.A.

By: */s/ L. Timothy Fisher*

L. Timothy Fisher (State Bar No. 191626)
1990 North California Blvd., Suite 940
Walnut Creek, CA 94596
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Attorneys for Plaintiffs

I, Allison Ottesen, declare as follows:

1. I am a plaintiff in this action and a citizen of the State of California. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would testify competently thereto.

2. The complaint filed in this action is filed in the proper place for trial under California Civil Code Section 1780(d) because I reside in this District and a substantial part of the events or omissions giving rise to these claims occurred in this District.

3. While living in Oakland, California, I purchased HydroxyElite supplements for personal use. I paid approximately $34.95 for the HydroxyElite supplements. I purchased the HydroxyElite supplements based on the understanding that the supplements were lawfully sold and did not contain illegal and unsafe stimulants. My belief that the HydroxyElite supplements I purchased were lawfully sold and free from unsafe and illegal stimulants was a substantial factor in my decision to purchase the HydroxyElite supplements. Had Defendant disclosed that the HydroxyElite supplements I purchased were unsafe and illegal, I would have been aware of that and would not have purchased the Supplements.

I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct, executed on October 31, 2019 at Oakland, California.

Allison Ottesen

EXHIBIT A

WARNING LETTER

Hi Tech Pharmaceuticals

MARCS-CMS 560788 — APR 10, 2019

Product:

Dietary Supplements

Recipient:

Jared Wheat

CEO & Founder

Hi Tech Pharmaceuticals

6015 B Unity Drive
Norcross, GA 30071-3575
United States

Issuing Office:

Center for Food Safety and Applied Nutrition

5001 Campus Drive
College Park, MD 20740-3835
United States

WARNING LETTER

VIA OVERNIGHT DELIVERY

RETURN RECEIPT REQUESTED

April 10, 2019

Jared Wheat, CEO & Founder

Hi-Tech Pharmaceuticals, Inc.

6015 B Unity Drive

Norcross, GA 30071-3575 US

Re: 560788

Dear Mr. Wheat:

This letter concerns your products Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene, which are labeled and/or offered for sale as dietary supplements. The Supplement Facts panel on your product labels declares 2-Aminoisoheptane HCl as a dietary ingredient. This ingredient is also called, among other names, 1,5-DMHA, 2-amino-6-methylheptane, 2-amino-5methylheptane, 1,5-Dimethylhexylamine, 2-Isooctyl amine, and Octodrine, and will be referred to hereinafter as DMHA.

The term "dietary supplement" is defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)]. Given that you have declared DMHA as a dietary ingredient in the labeling of your product, we assume you have a basis to conclude that DMHA is a "dietary ingredient" under section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)]. If you have a basis to conclude that DMHA is a "dietary ingredient," it would also be a "new dietary ingredient" (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) under section 413(d) of the Act [21 U.S.C. § 350b(d)].

Under section 413 of the Act [21 U.S.C. § 350b], a dietary supplement that contains a new dietary ingredient shall be deemed adulterated under section 402(f) of the Act [21 U.S.C. § 342(f)] unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that DMHA was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. Assuming DMHA is a dietary ingredient, in the absence of such information, DMHA would be subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. § 350b(a)(2)] and 21 CFR 190.6. Products for which the manufacturer or distributor is required to submit a new dietary ingredient notification under section 413(a)(2) and 21 CFR 190.6, but for which the required notification has not been submitted, are adulterated under sections 402(f) and 413(a) of the Act [21 U.S.C. §§ 342(f) and 350b(a)].

Even if a new dietary ingredient notification had been submitted under section 413(a)(2) and 21 CFR 190.6, we know of no evidence that would establish that DMHA could be lawfully marketed as a new dietary ingredient in your Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene products. In the absence of a history of use or other evidence of safety establishing that DMHA, when used under the conditions recommended or suggested in the labeling as a dietary ingredient, will reasonably be expected to be safe, dietary supplements containing DMHA as a new dietary ingredient are adulterated under sections 402(f) and 413(a) of the Act because there is inadequate information to provide reasonable assurance that such ingredient does not present

a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under sections 301(a) and (v) of the Act [21 U.S.C. § 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that DMHA will reasonably be expected to be safe when used as a dietary ingredient.

We also note that we have questions about whether DMHA is, in fact, a dietary ingredient. If DMHA were not a dietary ingredient under section 201(ff)(1) of the Act, it would be an unsafe food additive. If a substance is not generally recognized as safe (GRAS) by qualified experts for its intended use in food and does not qualify for any of the other exemptions from the food additive definition, it is a food additive.[1] Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in food is deemed to be unsafe and causes the food to be adulterated under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(C)(i)]. Adulterated foods cannot be legally imported or marketed in the United States.

Section 201(s) of the Act [21 U.S.C § 321(s)] exempts dietary ingredients used in dietary supplements from the food additive definition. However, non-dietary ingredients intended for use in dietary supplements are not exempt from the food additive definition and must meet the same requirements as substances added to conventional foods. In other words, a non-dietary ingredient added to a dietary supplement must be used in accordance with a food additive regulation or be GRAS for its intended use, unless it qualifies for another exception to the food additive definition.

DMHA it is not generally recognized as safe under its conditions of use in your dietary supplement products. If DMHA is not a dietary ingredient under section 201(ff)(1) of the Act, dietary supplements containing DMHA would be adulterated under section 402(a)(2)(C)(i) of the Act because they would contain an unsafe food additive.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations addressed in this letter, as well as any other violations associated with your Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene products or other dietary supplement products marketed by your firm, including any that contain DMHA. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. Failure to immediately cease distribution of your products Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene, and any other products you market that contain DMHA, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in

violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your written reply should be directed to Mr. Rob Genzel Jr., Compliance Officer, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, you may also contact Mr. Genzel at rob.genzel@fda.hhs.gov (mailto:rob.genzel@fda.hhs.gov).

Sincerely,

/S/

William A. Correll

Director

Office of Compliance

Center for Food Safety and Applied Nutrition

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[1] Under section 201(s) of the Act [21 U.S.C. § 321(s)], the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food; (2) pesticide chemicals; (3) color additives; (4) substances used in accordance with a "prior sanction" (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the Act, the Poultry Products Inspection Act, or the Meat Inspection Act); (5) new animal drugs; and (6) dietary ingredients in or intended for use in a dietary supplement.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

EXHIBIT B

BURSOR & FISHER
P.A.

888 SEVENTH AVENUE
NEW YORK, NY 10019
www.bursor.com

YITZCHAK KOPEL
Tel: 646.837.7127
Fax: 212.989.9163
ykopel@bursor.com

August 12, 2019

Via Certified Mail - Return Receipt Requested

Hi-Tech Pharmaceuticals
6015 B Unity Drive
Norcross, GA 30071

Re: Demand Letter Pursuant to Cal Civ Code § 1782; violation of the U.C.C. §§ 2-314; Cal Health & Saf Code § 110620; Cal Bus & Prof Code §§ 17200, 17500, et seq; Cal Civ Code §§ 1750, et seq; N.Y. G.B.L. §§ 349, 350; Fraud, Breach of Implied Warranty; and all other applicable laws

To Whom It May Concern,

This letter serves as a preliminary notice and demand for corrective action by Hi-Tech Pharmaceuticals, Inc. ("Defendant," "Hi-Tech" or "You") arising from violations of consumer protection laws on behalf of our clients, Sean Allen, Lauren Accardi, Jacob Radochonski, Allison Ottesen, and a class of all similarly situated purchasers of Hi-Tech's Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene supplements, as well as all other products containing the stimulant known as 2-aminoisoheptane ("DMHA[1]"). This letter also serves as notice pursuant to U.C.C. § 2-607(3)(a) concerning the breaches of implied warranties described herein. This letter additionally serves as notice of violations of all applicable consumer protection laws, including, but not limited to, California Business & Professions Code §§ 17200 & 17500, et seq, California Civil Code §§ 1750, et seq, and New York General Business Law §§ 349 & 350.

You have participated in the manufacture, marketing, and sale of Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene supplements, as well as other supplements containing the ingredient DMHA (collectively, "Supplements"). The above-referenced Supplements have been marketed and sold as part of fat-burning supplements or pre-workout formulations. However, pursuant to an April 10, 2019 warning letter from the United States Food and Drug Administration ("FDA") to Hi-Tech, "DMHA it is not generally recognized as safe under its conditions of use in [Hi-Tech's] dietary supplement products."[2] The FDA explained that, to the best of its knowledge, there is no evidence that "DMHA was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered."[3] Further, the

[1] DMHA is known by various names, including Octodrine. The term DMHA as used herein is designed to refer to DMHA collectively under its various names.
[2] The FDA's April 10, 2019 warning letter is attached hereto as **Exhibit A**.
[3] *See* Ex. A, at 2.

FDA concluded that "dietary supplements containing DMHA as a new dietary ingredient are adulterated . . . because there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."[4]

Published academic literature has confirmed the findings of the FDA, namely concluding that the "uncontrolled use of [DMHA], its physiological and psychoactive effects raise serious health implications with possible impact on athletes and doping practices."[5] DMHA has been associated with side effects such as "mood swings, tremor, concentration deficiency, over-stimulation, energy crashes, anxiety, high blood pressure, dyspnoea, rapid heartbeat and heartburn."[6]

DMHA has also been banned by most major associations in the United States and abroad, including the NCAA, United States/World Anti-Doping Agency, and the Department of Defense.

Additionally, the state of California adopts new federal food regulations 30 days after any federal regulation takes effect pursuant to California Health & Safety Code § 110115. Finally, according to California Health & Safety Code § 110620, it is unlawful to sell any adulterated food, which is defined by California Health & Safety Code § 110545 as any food that "bears or contains any poisonous or deleterious substance that may render it injurious to [the] health of man." Taken together these statutes mean that it unlawful to sell goods that are against FDA regulations in the state of California.

Mr. Allen, Mr. Radochonski, Ms. Accardi, and Ms. Ottesen each purchased Hi-Tech supplements containing the unlawful ingredient DMHA. Had they known the truth about the supplements, they would not have purchased or used the products.

By selling adulterated and illegal supplements to our clients and others similarly situated, Hi-Tech breached implied warranties made to consumers. *See* U.C.C. § 2-313. Hi-Tech failed to inform consumers of the true nature of, and danger associated with, DMHA.

Defendant's conduct is also a deceptive business practice under all applicable consumer protection laws, including, but not limited to, California Business & Professions Code §§ 17200 & 17500, et seq, California Civil Code §§ 1750, et seq, and New York General Business Law §§ 349 & 350.

Our clients are acting on behalf of a class defined as all persons in the United States who purchased and used the Supplements. Additionally, Jacob Radochonski and Allison Ottesen are acting on behalf of a subclass of all persons in California who purchased and used the Supplements. Sean Allen and Lauren Accardi are acting on behalf of a subclass of all persons in New York who purchased and used the Supplements.

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[4] *Id.* at 2-3.
[5] Catalani, Valeria et al. "Octodrine: New Questions and Challenges in Sport Supplements." *Brain sciences* vol. 8,2 34. 20 Feb. 2018, doi:10.3390/brainsci8020034
[6] *Id.*

To cure these defects, we demand that you (1) cease and desist from further sales of the mislabeled Supplements; (2) issue an immediate recall of the Supplements; and (3) make full restitution to all purchasers of the Supplements.

We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the design, development, supply, production, extraction, and/or testing of the Supplements;

2. All documents concerning the advertisement, marketing, or sale of the Supplements;

3. All documents concerning communications with any retailer involved in the marketing or sale of the Supplements;

4. All documents concerning communications with purchasers of the Supplements;

5. All adverse event reports or consumer complaints regarding the Supplements;

6. All documents concerning communications with federal or state regulators; and

7. All documents concerning the total revenue derived from sales of the Supplements in the United States.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents promptly.

This letter also serves as a thirty (30) day notice and demand under California Civil Code § 1782 for damages. Accordingly, should you fail to rectify the situation on a class-wide basis within 30 days of receipt of this letter, we will seek actual damages, plus punitive damages, interest, attorneys' fees and costs.

We are willing to negotiate to attempt to resolve the demands asserted in this letter. If you wish to enter into such discussions, please contact me right away. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Yitzchak Kopel